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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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R. Neil Sudol 7590 04/17/2008				
714 Colorado Avenue				
Bridgeport, CT 06605-1601				
EXAMINER				
BEISNER, WILLIAM H				
ART UNIT		PAPER NUMBER		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/825,413

**Applicant(s)**

GOMEZ ET AL.

**Examiner**

WILLIAM H. BEISNER

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**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2, 4-19, 21-24, 26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-19, 21-24, 26 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/808)  
Paper No(s)/Mail Date 1/7/2008.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement filed 1/7/2008 has been considered and made of record.

### ***Specification***

2. The amendment filed 1/7/2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Amended paragraph 0084 recites a plurality of cavities or chambers connected to one another using a branching channel structure. This language is considered new matter because the originally filed disclosure fails to support this new language. The originally filed disclosure only discloses a plurality of channels or chambers connected in series. Note the embodiment associated with Figure 21 indicates that separate channels are used with the detection and reference chambers.

Applicant is required to cancel the new matter in the reply to this Office Action.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 19, 21-24, 26 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 19 as currently amended requires that a plurality of detection chambers are connected to one another using a branching channel structure including at least one large inflow groove or trench and a substantially smaller channel extending from the inflow groove or trench to the detection chambers. The originally filed disclosure (specification, figures and claims) fails to support this newly recited claim limitation. As shown in Figure 1, while a plurality of chambers are connected to one other only the first and last channels includes a branching channel structure including a large inflow groove or trench and a substantially smaller channel. As a result, the originally filed disclosure fails to reasonably convey to one skilled in the art, at the time the application was filed, had possession of the claimed invention encompassed by claims 19, 21-24, 26 and 27.

#### ***Double Patenting***

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1, 2, 4, 7-19, 21, 24, 26 and 27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,716,620. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 1, 2, 4, 7-19, 21, 24, 26 and 27 are generic to all that is recited in claims 1-20 of U.S. Patent No. 6,716,620. That is, claims 1-20 of U.S. Patent No. 6,716,620 fall entirely within the scope of claims 1, 2, 4, 7-19, 21, 24, 26 and 27 or, in other words, claims 1, 2, 4, 7-19, 21, 24, 26 and 27 are anticipated by claims 1-20 of U.S. Patent No. 6,716,620.

7. Claims 5, 6, 22 and 23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,716,620 in view of Miles et al.(US 6,576,459).

Claims 1-20 of U.S. Patent No. 6,716,620 encompass a device that is substantially the same as that instantly recited in instant claims 5, 6, 22 and 23.

Claims 5, 6, 22 and 23 differ by reciting that the retention device includes electrodes for generating a non-uniform electric field to retain the microorganisms.

The reference of Miles et al. discloses that it is known in the art to collect desired analytes on carrier beads within a non-uniform electric field (See the Figure and column 5, lines 27-52).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a non-uniform electric field retention device in the system of the primary reference for the known and expected result of providing an alternative means recognized in the art for retaining a desired analyte to be detected within a microfluidic device. Note the field is capable of being applied periodically.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 5, 6, 22 and 23 are rejected under 35 U.S.C. 103(a) as being obvious over Bashir et al.(US 6,716,620) in view of Miles et al.(US 6,576,459).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter

disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The reference of Bashir et al. discloses a device that is substantially the same as that instant claimed. The reference discloses a collection chamber (34) with a microchannel inlet and outlet (See Figure 19). The reference discloses a retention structure that include means for generating a magnetic field (See column 28, line 53, to column 29, line 43).

With respect to claims 5, 6, 22 and 23, while the reference discloses a magnetic retention device in the collection chamber, the instant claims differ by reciting the use of a device for generating a non-uniform electric field.

The reference of Miles et al. discloses that it is known in the art to collect desired analytes on carrier beads within a non-uniform electric field (See the Figure and column 5, lines 27-52).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a non-uniform electric field retention device in the system of the primary reference for the known and expected result of providing an alternative means recognized in the art for retaining a desired analyte to be detected within a microfluidic device.



***Response to Arguments***

12. With respect to the rejection of Claims 20-24 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, the rejection of the claims has been withdrawn in view of Applicants' amendments to the claims and related comments (See page 10 of the response filed 1/7/2008).

13. With respect to the rejection of Claims 1-4, 7-21 and 24-27 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,716,620 and Claims 5, 6, 22 and 23 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,716,620 in view of Miles et al.(US 6,576,459), Applicants have indicated that a Terminal Disclaimer has been filed (See page 11 of the response filed 1/7/2008). No such Terminal Disclaimer is currently of record in the instant application.

14. With respect to the rejection of Claims 1, 2, 8-12, 14, 15, 18-21, 24 and 27 under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al.(US 6,143,247) in view of Wilding et al.(US 5,726,026); Claims 10-16 under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al.(US 6,143,247) in view of Wilding et al.(US 5,726,026) and Feldberg (US 5,824,494); Claims 17 and 26 under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al.(US 6,143,247) in view of Wilding et al.(US 5,726,026) and Hintsche et al. (US 5,670,031); and

Claims 22 and 23 under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al.(US 6,143,247) in view of Wilding et al.(US 5,726,026) and Miles et al.(US 6,576,459), these rejections have been withdrawn in view of Applicants' amendments to the claims and related comments (See pages 11-14 of the response filed 1/7/2008). Note claims 19, 21-24, 26 and 27 have been rejection under 35 USC 112, first paragraph, because the amendment to claim 19 is considered new matter.

15. With respect to the rejection of Claims 5, 6, 22 and 23 under 35 U.S.C. 103(a) as being obvious over Bashir et al.(US 6,716,620) in view of Miles et al.(US 6,576,459), Applicants have indicated that a Declaration under 37 CFR 1.130 has been filed (See page 14 of the response filed 1/7/2008). No such Declaration is currently of record in the instant application.

### ***Conclusion***

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM H. BEISNER whose telephone number is (571)272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/William H. Beisner/  
Primary Examiner  
Art Unit 1797**

WHB